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10/668,750

09/23/2003

Victor E. Kimball

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EXAMINER

NASSER, ROBERT L

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

06/22/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/668,750 | Applicant(s) KIMBALL ET AL. | |
| | Examiner Robert L. Nasser | Art Unit 3735 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 and 61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38, 61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-38 and 61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In addition, the claims recite determining the degree of perfusion when flow is substantially below normal and PCO₂ is substantially above normal and/or the pH is substantially below normal. However, nowhere in the specification does applicant teach conditionally determining the degree of perfusion, i.e. only determining the degree of perfusion failure when the conditions are met. The specification teaches that the conditions are indicative of perfusion failure, but not that the degree of perfusion is measured. Since this limitation was added via amendment, it constitutes new matter.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-29, 33-35, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosenberg et al 4538618, or in the alternative under 103(a) as being unpatentable over by Rosenberg et al. With respect to claim 1, Rosenberg has a blood flow sensor, i.e. fiber 16, located in a measuring head 2 and an indicator 36, for indicating the blood flow measurement. The device further includes a PCO2 sensor (see column 5, line 55). It is the examiners position that there would also be an indicator for indicating the PCO2 measurement, given that the reference provides an indicator for all of the other measured values. Alternatively, the examiner takes official notice that it is well known to display measurement values in medical devices, to inform the user and/or the physician of the patient's condition. The examiner notes that the degree of systemic perfusion, i.e. the blood flow, is displayed all the time including when the recited conditions are met. Claims 2-21 are rejected in that the device is capable of being positioned adjacent any of the mucosal surfaces recited. With respect to claims 23-27, the examiner notes that the positioning means recited in the specification is a structure that holds the sensor in place when in use. However, the "positioning" function is an intended use limitation. In order to meet the claim language, the

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reference need only have a structure that is capable of performing that function. In Rosenberg, element 4 or element 26 both are devices that are capable of being used to hold the sensor in position adjacent a mucosal surface. As such, Rosenberg meets the intended function of the positioning means and meets the claim limitation. With respect to claims 28 and 29, the flow sensor is laser-doppler or ultrasonic (see column 5, lines 43-50). Claims 33-35 are rejected in that in addition to the features discussed above, the sensor holder is "shaped" to fit under the tongue and support the tongue, and includes a back surface, or "slot" that is capable of receiving the frenulum. The examiner notes that the phrase "shaped to fit" is being interpreted as meaning only capable of fitting. The examiner suggests that applicant recite that the sensor holder has a shape corresponding to the shape of the area under the tongue or use similar language. Claim 38 is rejected for the reasons given above.

Claims 30 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg et al in view of Riccitelli et al 5166990. Riccitelli et al further teaches that it is known to monitor pH and PCO₂ in the same intravascular measuring device. As such, it would have been obvious to modify Rosenberg to include a pH sensor, to provide a more complete picture of the patient's condition.

Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenberg et al in view of Boggett et al WO 98/20794. Boggett et al further teaches that in a microvascular monitoring device like that of Rosenberg, that it is known to monitor the rate of change of blood flow. As such, it would have been obvious

to modify Rosenberg to include a rate of change of flow determining device, to provide a more complete picture of the patient's condition.

Claims 33-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Millar 4966148. Millar shows a device including a blood flow sensor and a sensor holder 20 that is capable of holding the device in place, as discussed with respect to Rosenberg above. Millar does not state that it has an indicator. However, the examiner takes official notice that it is well known to display measurement values in medical devices, to inform the user and/or the physician of the patient's condition. The examiner notes that the degree of systemic perfusion could then be deduced from the indicator. With respect to claim 37, Millar teaches a device with a flow sensor and a pH sensor (see column 2, lines 28-49). Again, it would have been obvious to include the indicator, as discussed above.

Applicant's arguments filed 4/10/2007 and 8/2/2006 have been fully considered but they are not persuasive.

With respect to the written description rejection above, applicant pointed to a portion of the specification which allegedly supported the indicating the degree of systemic perfusion when, i.e only if, certain conditions are met. However, it is the examiner's position that the specification states that perfusion failure is indicated if the condition is met, and there is no disclosure of conditionally indicating the degree perfusion.

Referring back to the arguments filed on 8/2/2006, applicant has asserted that Rosenberg does not indicate a degree of perfusion when the conditions are met.

The examiner notes that Rosenberg provides an indication of the degree of perfusion all the time, including when the conditions are met.

Applicant's arguments concerning claim 37 fail for the same reason given above, i.e. the combination of Rosenberg and Miller indicate the degree of perfusion all the time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is 571 272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Robert L. Nasser

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Primary Examiner
Art Unit 3735

RLN
June 20, 2007

A handwritten signature in black ink, appearing to read "Robert L. Nasser", with a stylized flourish at the end.

ROBERT L. NASSER
PRIMARY EXAMINER